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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,823	11/19/2003	Robyn Sackeyflo	50164/006004	7193
21559	7590	09/07/2005	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			GEORGE, KONATA M	
		ART UNIT		PAPER NUMBER
		1616		

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/716,823	SACKYFLO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-34 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

## DETAILED ACTION

Claims 1-34 are pending in this application.

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on January 12, 2004 and July 1, 2004 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 7-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 8-10, 15-17, 20 and 23-29 of U.S. Patent No. 6,897,206 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application

and the prior art are drawn to the essentially the same invention, a method of treating an inflammatory disorder by administering a tricyclic antidepressant and a corticosteroid simultaneously or within 14 days of each other.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by International Journal of Dermatology (1999).

Claim 1 is directed towards a composition for systemic administration comprising a tricyclic antidepressant and a corticosteroid. Claims 2 and 4 are directed towards a low dose of the corticosteroid. Claim 3 is directed towards the tricyclic antidepressant is selected from the group consisting of maprotiline, amoxapine, etc.

The prior art teaches a method of treating 349 patients with atopic dermatitis with a composition containing a tricyclic antidepressant and a corticosteroid. Of these 349 patients 90 were treated with a combination of triamcinolone (i.e. corticosteroid) and doxepin hydrochloride (i.e. antidepressant) (see abstract). It is also taught that 86 patients were treated with a combination of hydrocortisone and doxepin hydrochloride.

Page 146, second column last paragraph teaches the composition is administered

topically. Although the prior art does not teach the composition is administered systemically, examiner interprets "systemic administering" as the drug composition entering the circulatory system. It is the position of the examiner that as the composition of the prior art is applied to the skin topically, it is absorbed into the skin and thus into the circulatory system via capillaries. Furthermore, it is not defined in the specification what modes of delivery are defined as "systemic".

4. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (US 5,900,249).

Claim 5 is directed towards a composition for topical administration comprising a tricyclic antidepressant and a corticosteroid, wherein the tricyclic antidepressant is selected from the group consisting of maprotiline, amoxapine, etc. Claim 6 is directed towards a low dose of the corticosteroid.

Smith discloses a topical medication comprising four components: 1) vasodilator, 2) NSAID, 3) membrane stabilizer and 4) seratogenic and nonadrenergic reuptake inhibitor and additionally a medically acceptable carrier (col. 2, lines 49-55). Smith teaches examples of seratogenic and nonadrenergic reuptake inhibitors can be tricyclic antidepressants such as amoxapine (col. 5, lines 2-10). It is further taught in column 2, lines 11-56 that it is advantageous to contain either or both a topical anesthetic and an anti-inflammatory steroid. Examples of anti-inflammatory steroids are hydrocortisone, predneisolone, etc. and can be at a low concentration of 0.5% by weight.

***Conclusion***

5. Claims 1-34 are rejected.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

*Gary L. Kunz*  
GARY KUNZ  
SUPPLYORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600